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EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/338,063

Applicant(s)
Goto et al.

Examiner
G. R. Ewoldt

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/15/01, 4/23/01, 5/07/01
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-49 is/are pending in the application.
- 4a) Of the above, claim(s) 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/915,004.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 923
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. The request filed on 2/15/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/338,063 is acceptable and a CPA has been established. An action on the CPA follows.

2. A restriction was required under 35 U.S.C. § 121 in the parent application, as set forth in Paper No. 6, mailed 11/17/99.

Applicant elected Group I, claims 32-35, drawn to an antibody, with traverse. This restriction requirement is hereby reiterated.

The requirement is still deemed proper for the reasons of record as set forth in Paper No. 8, mailed 2/10/00, and is therefore made FINAL.

3. Claim 36 stands withdrawn from further consideration by the examiner as being drawn to non-elected invention.

Claims 37-49 are being acted upon.

4. In view of Applicant's amendment and cancellation of all previously pending claims, filed 5/07/01, all previous rejections have been withdrawn.

5. The disclosure is objected to because of the following informalities:

The repeated use of the trademarks "MICROTITER", "IMMUNOPURE", "SEPHAROSE", "PBLUESCRIPT", "QIAEX", "READY-TO-GO", "PROBLOTT", "OPTI-MEM", and "ZAP EXPRESS" has been noted in this application. They should be capitalized and accompanied by the TM or ® symbol wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required. Applicant is further notified that should a significant number of substitute amended paragraphs be submitted, said substituted amended paragraphs will not be entered into the specification and another substitute specification will be required.

6. The following are New Grounds of Rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 37-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridomas FERM BP-7441, FERM BP-7442, and FERM BP-7443 are required to practice the claimed invention. As a required element, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If the deposit was made under the provisions of the Budapest Treaty, then an affidavit or declaration to that effect is required. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Although the claimed hybridomas are on deposit, there appears no assurances as indicated above. Applicant's provision of these assurances through the submission of an appropriate declaration would obviate this rejection.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, as written, points (a) -(d) of the claim read on the claimed monoclonal antibody and not the protein it binds as Applicant presumably intends. Additionally, the

phrase "said monoclonal antibody comprises a binding site selected from the group consisting of A1GF having accession No. FERM BP-7441, D2F4 having accession No. FERM BP-7442, E3H8 having accession No. FERM BP-7443," is nonsensical as the members of the Markush grouping are hybridomas and not antibodies or binding sites. Further, "A1GF" should presumably be A1G5.


11. No claim is allowed.

12. Hybridomas A1G5 having accession No. FERM BP-7441, D2F4 having accession No. FERM BP-7442, E3H8 having accession No. FERM BP-7443 appear to be free of the prior art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center at (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
August 9, 2001


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600